K062483

510(k) Summary

SEP - 8 2006

Administrative Information and Device Identification

Name and address of the manufacturer and sponsor of the 510(k) submission:	Line Ind. (Shanghai) Co., Ltd. 168 XinSheng Road, ZhaoTun Zhen QingPu Qu, Shanghai -- 201700, China
Official contact person for all correspondence:	Brendan Lee Phone: 86-21-59228688-1700 Fax: 86-21-59228922 E-mail: brendanlee@care-line.co.kr
Date Prepared:	July 19, 2006
Device Name:	Mini Power Chair MN 5000
Generic name of the device:	Powered wheelchair
Classification of new device:	Class II
Classification Panel:	Physical Medicine
Product Code and CFR Regulation Number:	ITI and 21 CFR 890.3860
Predicate Device Name and 510(k) Number:	PHFW-10; K022539

Description of Device:

The Mini Power Chair MN 5000 is an indoor/outdoor powered wheelchair that is battery operated. It has four wheels and anti-tip. The design of this wheelchair is basically similar to other power chairs that are already on the market. But the MN 5000 is kind of a new class of lightweight power chair. By providing a power chair that breaks down into four manageable components(seat, battery pack, front frame and rear frame), a user can have a more practical alternative when traveling long distances by auto, bus, train, etc.. MN 5000 achieves it by using a lightweight tubular design with quick disapart front and rear frames, easily detachable seat and a quick release battery pack system.

MN 5000 has two motors, an off-board battery charger, a fully programmable controller, and a removable battery pack.

The wheelchair has a sturdy base which contains the motors, provides space for the battery box and supports the padded seat. The breaking system is automatic and electric. The seat has adjustable armrest and footrest. There is a controller with a joystick that attaches to either armrest and allows the rider to control the movement of the power chair. The Drive wheels (rear wheels) are 8" in diameter and the Caster wheels (front wheels) are 6".

Comparison of Device Technological Characteristics to Predicate Device:

The device has similar technological characteristics as the predicate device. They all use steel in their frames and components, and standard foams and covers for the slings, backs and cushions. Microprocessors are typically used with a programmable controller, and the end-user controls the chair by using a joystick or other equivalent command mode. Motors use 24volt DC rechargeable batteries for an energy source. The operating speeds, maneuverability, power modules, hand controls, seat types, drive wheels, and climbing ability are substantially equivalent and are recommended for indoor and moderate outdoor use. The standard accessories and components are common to all power wheel chair devices.

The Mini Power Chair MN 5000 uses the VR2 controller while the predicate uses VSI. Both controllers are from the same manufacturer and have basically the same functionality. The changes are mainly related to size, ergonomics and enhancement of existing features. Verification and validation testing confirms that a wheelchair fitted with VR2 performs as intended.
A shorter range of operation, along with a more portable and light weight design allows the Mini Power Chair MN 5000 to use less powerful batteries when compared to the predicate device. Detailed testing has confirmed that these changes do not affect the performance or safety of the wheelchair.

Intended Use:

The Mini Power Chair MN 5000 is intended to provide mobility to persons limited to a sitting position, that have the capability of operating a powered wheelchair. The Mini Power Chair MN 5000 provides an optional means of mobility for physically challenged people.

Non-Clinical Testing:

Following FDA's recommended list of testing in the classification database for Powered wheelchairs, the device has been tested to appropriate ISO & ANSI/RESNA standards. Among other things, tests were conducted to evaluate the static and dynamic stability of the wheelchair, its energy requirements, performance of breaks etc. It passes EMC requirements. Flame retardant tests of the upholstery materials also meet requirements.

Clinical Testing:

Not applicable

Conclusion:

The MN 5000 is substantially equivalent to the predicate device listed in this Summary and the device, as changed, does not raise any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 2006

Line Ind. (Shanghai) Co., Ltd
% Intertek Testing Services
Mr. Daniel W. Lehtonen
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K062483
Trade/Device Name: Mini Power Chair MN 5000
Regulation Number: 21 CFR 890.3860
Regulation Name: Powered wheelchair
Regulatory Class: Class II
Product Code: ITI
Dated: August 24, 2006
Received: August 25, 2006

Dear Mr. Lehtonen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit C

INDICATIONS FOR USE

510(k) Number (if known): Not Assigned as of this time

Device Name: MINI POWER CHAIR MN 5000

Indications for Use:

The Mini Power Chair MN 5000 is intended to provide mobility to persons limited to a sitting position, that have the capability of operating a powered wheelchair. The Mini Power Chair MN 5000 provides an optional means of mobility for physically challenged people.

Prescription Use _____
(Per 21 CFR 801 Subpart D)

OR

Over-The Counter Use X
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bucinski for M&M

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

May 10, 2006
Line Ind.(Shanghai) Co., Ltd.

510(k) Number K062483